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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,193	12/05/2003	Ping Wang	50425/187	2406
7590	08/11/2004			EXAMINER MAYER, SUZANNE MARIE
Elie H. Gendloff, Ph.D., Esq. Amster, Rothstein & Ebenstein, LLP 90 Park Avenue New York, NY 10016			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/729,193	WANG, PING	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4,9-11,13 and 16-20 is/are rejected.
- 7) Claim(s) 3,5-8,12,14 and 15 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 17 recites the limitation "the another treatment" in reference to claim 16. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 9-11, 13, 16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. Yang et al. teach the co-administration of adrenomedullin binding protein-1 (AMBP-1) and adrenomedullin (AM) after the on-set of sepsis in concentrations of 12 µg/kg and 40µg/kg, respectively (see Abstract).

Claims 1 and 2 are rejected because one suffering from sepsis is at risk for the on-set of septic shock. Furthermore, the claim language of 'comprising' is

open and therefore for these claims to be anticipated one only needs to find a composition containing AMBP-1 and AM.

Claim 4 is rejected because Yang et al. teach that they use commercially available AMBP-1 and AM that are synthetic peptides derived from rats. Since AM and AMBP-1 from rats are identical, then it can be concluded that synthetic rat AM and AMBP-1 are inherently derived from whichever species that one is using. In the instant case, Yang et al. use Sprague-Dawley rats.

Claim 9 is rejected because Yang et al. teach that administration of AMBP-1 and AM affects systemic oxygen delivery (p. 2730, last paragraph).

Claims 10 and 11 are rejected because Yang et al. teach the administration of AMBP-1 and AM at concentrations of 12  $\mu$ g/kg and 40 $\mu$ g/kg, respectively (see Abstract).

Claim 13 is rejected because administration of AMBP-1 and AM is taught by Yang et al. to be administered during sepsis, and therefore septic shock has not been initiated yet.

Claim 16 is rejected as it recites the method of claim 1 wherein AMBP-1 is administered with another agent that reduces physiological effect of shock. In this case, the agent taught by Yang et al. is AM.

Claims 18-20 are rejected on the same basis as described above for claims 1, 2 and 9.

***Conclusion***

5. Claims 1, 2, 4, 9-11, 13, and 16-20 are rejected. Claims 3, 5-8, 12, 14 and 15 are objected to because they depend from rejected claims but would be allowable if rewritten in independent form.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached Monday to Friday from 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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30 July, 2004



ROBERT A. WAX  
PRIMARY EXAMINER